MAY 2 4 2001

# 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K010858.

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| **Submitter:** | ID Biomedical Corporation<br>1510 – 800 West Pender<br>Vancouver, British Columbia<br>Canada V6C 2V6<br>Telephone: (604) 431-9314<br>Fax: (604) 431-93789 |
| **Establishment Registration Number** | 3033040 |
| **Contact Person:** | David N. Clary, Regulatory Affairs Associate<br>ID Biomedical Corporation of Washington<br>19204 North Creek Parkway<br>Suite 100<br>Bothell, WA 98011<br>Telephone: (425) 482-2601, Ext. 424<br>Fax: (425) 482-2502 |
| **Date Prepared:** | March 19, 2001 |
| **Trade Name:** | Velogene™ Genomic Identification Assay for MRSA with One-Step Detection |
| **Common Name:** | Manual genomic identity test |
| **Device Class** | II |
| **Classification Name:** | Manual antimicrobial susceptibility test system |
| **Special Controls** | No special controls have been issued for *in vitro* diagnostic devices under sections 513 and 514. |

## INTENDED USE

The Velogene™ Genomic Identification Assay for MRSA with One-Step Detection is a qualitative DNA probe test which utilizes Cycling Probe™ Technology (CPT) to detect the *mecA* gene in isolated colonies of presumptively identified *Staphylococcus aureus*.

# DEVICE DESCRIPTION

The Velogene™ Rapid MRSA (Methicillin Resistant *Staphylococcus Aureus*) Identification Assay with One-Step Detection is an *In-vitro,* DNA probe based, diagnostic device that utilizes Cycling Probe™ Technology (CPT) to generate a result that can be read visually. This visual result can be generated 90 minutes after primary isolation.

Each Velogene™ Genomic Identification Assay for MRSA with One-Step Detection assay kit contains supplies sufficient to process 48 samples and consists of two separate reagent kits: an MRSA Lysis/Cycle Kit and an MRSA One-Step Detection Kit.

### MRSA Lysis/Cycle Kit

The Lysis/Cycle kit contains the reagents and components to lyse the sample cells from an overnight culture of *S. aureus* and complete the Cycling Probe™ Technology (CPT) process.

CPT utilizes a fluorescein labeled biotinylated DNA-RNA-DNA chimeric probe that binds to the complementary sequence of the *mecA* gene in samples that are *mecA* positive. When the probe has hybridized with the target DNA, the enzyme RNase H cleaves the RNA portion of the chimeric probe. This results in a fluorescein labeled fragment and a biotinylated fragment. The cleaved probe disassociates from the target DNA allowing the probe cleavage cycle to be repeated. If the sample is *mecA* negative, the chimeric probes remain intact.

### MRSA One-Step Detection Kit

The detection kit contains nitrocellulose immunochromatographic strips that are inserted into the test solution. Mouse anti-fluorescein-gold particles (Anti-F-GP) present in the conjugate pad bind with the fluorescein on cleaved fragments and uncleaved probes. As the solution flows through the strip, a streptavidin band in the "RESULT" section of the strip captures the biotinylated end of the chimeric probes. If the chimeric probe is intact, Anti-F-GP particles will be present and result in the formation of a test line. This test line indicates the absence of the *mecA* gene in the sample.

The lack of test line development indicates the presence of *mecA* gene in the sample. The Anti-F-GP particle/cleaved probe fragment complex will not have the biotinylated portion of the chimeric probe; therefore this complex will not bind to the streptavidin band.

A control line results from the binding of Anti-F-GP particles to rabbit-anti-mouse-IgG present on the nitrocellulose strip in the "CTRL" section. This indicates a normal flow of the reagents through the strip.

# PREDICATE DEVICES

The predicate devices for ID Biomedical's Velogene™ Genomic Identification Assay for MRSA with One-Step Detection are:

- Oxacillin Screen Agar (Mueller Hinton Agar with 4% NaCl and Oxacillin (6 µg/mL), #K863821, a NCCLS approved test for detection of Methicillin Resistant *Staphylococcus Aureus* (MRSA).
- ID Biomedical's Velogene™ Genomic Identification Assay for MRSA, #K990640, cleared 07/09/99.

# SUMMARY OF SUBSTANTIAL EQUIVALENCE

## Oxacillin Screen Agar

Oxacillin screen agar is a growth based test which phenotypically identifies methicillin resistance mediated through either the expression of the *mecA* gene that codes for the PBP2a, hyper β-lactamase production (HBLP), or the possession of modified penicillin binding proteins 1, 2 and 4 (MOD-SA).

Oxacillin screen agar is inoculated with a suspension of an overnight culture of *S. aureus* and plates are examined for evidence of growth at least 24 hours after primary culture isolation; growth in the presence of oxacillin indicates resistance to methicillin.

Both the Oxacillin screen agar and the Velogene™ Genomic Identification Assay for MRSA with One-Step Detection require isolates to be presumptively identified as coagulase positive *S. aureus* and both tests identify methicillin resistance in *S. aureus* resulting from expression of the *mecA* gene.

A comparative study was performed at three sites using a well-characterized collection of isolates prepared from samples routinely submitted for microbiological identification at four geographically distributed North American labs. The clinical isolates were previously characterized by oxacillin screen agar, broth microdilution[5] and detection of the *mecA* gene by a validated PCR assay. All isolates were tested blind. An agreement of 98% was obtained between the Velogene™ Genomic Identification Assay for MRSA with One-Step Detection and the Oxacillin Screen Agar when 456 isolates of coagulase positive *S. aureus* were tested (447 of 456).

ID Biomedical Corporation believes that the Velogene™ Genomic Identification Assay for MRSA with One-Step Detection is substantially equivalent in performance to oxacillin screen agar for detecting methicillin resistance (i.e. *mecA*) in presumptively identified colonies of coagulase positive *Staphylococcus aureus*.

## ID Biomedical's Velogene™ Genomic Identification Assay for MRSA

The Velogene™ Genomic Identification Assay for MRSA also genotypically identifies methicillin resistance by detecting the nucleotide sequence specific for the *mecA* gene using Cycling Probe™ Technology (CPT). The only notable difference is the detection method: the Genomic Identification Assay isolates the probes in a microtiter well instead of an immunochromatographic strip and the Anti-fluorescein antibodies are conjugated with horseradish peroxidase instead of gold particles.

The indication and intended use are the same.

The Velogene™ Genomic Identification Assay for MRSA was cleared based on substantial equivalence to Oxacillin Screen Agar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 24 2001

Mr. David N. Clary
Regulatory Affairs Associate
ID Biomedical Corporation
19204 North Creek Parkway, Suite 100
Bothell, Washington 98011

Re: 510(k) Number: K010858
Trade/Device Name: Velogene™ Genomic Identification Assay for MRSA with One-Step Detection
Regulation Number: 866.1640
Regulatory Class: II
Product Code: MYI
Dated: March 19, 2001
Received: March 22, 2001

Dear Mr. Clary:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# INDICATIONS FOR USE

**Applicant:** ID Biomedical Corporation, Vancouver, British Columbia, V6C 2V6 Canada

**510(k) Number:** K010858

**Device Name:** Velogene™ Genomic Identification Assay for MRSA with One-Step Detection

**Indications For Use:**

For the detection of the *mecA* gene in determining methicillin resistance in *staphylococcus aureus* isolated from culture.

Freddie Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010858